IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

MICROAIRE SURGICAL INSTRUMENTS, LLC, *Plaintiff,* v. ARTHREX, INC., *Defendant.*	CASE NO. 3:09-cv-00078 MEMORANDUM OPINION JUDGE NORMAN K. MOON

This matter is before the Court upon the Plaintiff MicroAire Surgical Instruments LLC's ("MicroAire") Motion for Preliminary Injunction and Memorandum of Points and Authorities in Support of Motion for Preliminary Injunction (docket nos. 6, 7), Defendant Arthrex, Inc.'s ("Arthrex") Opposition to MicroAire Surgical Instruments LLC's Motion for Preliminary Injunction (docket no. 18), MicroAire's Reply Brief on Motion for Preliminary Injunction (docket no. 23), and Arthrex's Notice of Filing certain declarations in response thereto (docket no. 28). After full consideration of the arguments set forth therein, and presented at oral argument in this matter, for the following reasons, the Court will DENY the Plaintiff's Motion for Preliminary Injunction, in an accompanying Order, to follow.

The Court concludes, *infra*, that MicroAire has not established that it is likely to succeed on the merits. In particular, the disputed term "actuating means" is properly construed as disclaiming any claim to "actuating means" by which the blade of the surgical instrument moves distally (forward) relative to the body of the instrument during its elevation. The disputed term "essentially perpendicular" is properly construed as only reciting that the blade follows a path which is in

essence at a right angle to the longitudinal axis of the instrument, and not a path which necessarily forms a right angle with the longitudinal axis. As Arthrex's allegedly infringing surgical instrument employs "actuating means" by which the blade moves distally relative to its body during elevation (even though its blade follows a path which is in essence at a right angle to the instrument's longitudinal axis) MicroAire has not established a claim of literal infringement of its patent, or infringement under the doctrine of equivalents. Furthermore, the Court concludes that MicroAire has not established that it is likely to suffer irreparable harm in the absence of preliminary relief, whether such harm is based upon the threatened loss of goodwill, irreversible price erosion in the market for this type of surgical instrument, or general decline in reputation of the surgical procedure at issue. Either MicroAire's failure to establish a likelihood of success on the merits, or its failure to establish a likelihood of irreparable harm, by itself, would justify the Court's denial of a preliminary injunction. Consideration of the remaining two factors the Court must consider in determining whether to issue a preliminary injunction, being the balance of equities and whether the injunction is in the public interest, do not compel a contrary result.

Accordingly, the Court will DENY MicroAire's Motion for Preliminary Injunction, in an accompanying Order, to follow.

I. BACKGROUND

MicroAire is a Delaware limited liability company that has its principal place of business in Charlottesville, which has been engaged in the business of manufacturing power-operated instruments for orthopedic surgery since 1977. On December 29, 1998, MicroAire acquired United States Patent No. 5,306,284 ("the '284 Patent") in connection with the acquisition of a carpal tunnel release instrument from Minnesota Mining and Manufacturing Company ("3M"). This carpal tunnel release instrument is covered in the United States by the '284 Patent, and is currently being sold by

MicroAire under its CTRS brand. The application for the '284 Patent was filed February 19, 1992, the Patent itself was issued April 26, 1994, and patent protection will expire February 19, 2012. The MicroAire CTRS product is a surgical instrument used for endoscopic carpal tunnel release surgery.

Carpal tunnel syndrome is a condition caused when the fibrous tissue surrounding one's wrist becomes inflamed, and places chronic pressure on the median nerve. The median nerve passes through a tight space, known as the carpal tunnel, between one band of tissue (the transverse carpal ligament) and the wrist bone. The symptoms of carpal tunnel syndrome may begin gradually, with frequent burning, tingling, or itching numbness in the palm and fingers, but without treatment, may develop into pain, weakness, and the wasting away of muscles in the hand. One course of treatment for carpal tunnel syndrome is through a procedure known as carpal tunnel release, which involves severing the transverse carpal ligament in order to relieve pressure on the median nerve. This procedure can be accomplished by use of a surgical device attached to an endoscope, which is essentially a small tube with a camera attached. There are different techniques for endoscopic carpal tunnel release surgery, either by making a small incision in the wrist (the "single-portal" technique), or by making small incisions in the wrist and palm (the "two-portal" technique). Like other endoscopic surgical procedures, carpal tunnel release can provide a patient numerous advantages over traditional surgical procedures, as the incision required in the hand is much smaller, and consequently, the possibility of visible scarring also likely decreased.

The '284 Patent relates to a surgical instrument for "probing body cavities and manipulating tissue contained therein under continuous observation." '284 Patent, col. 1, ll. 6-8. While the invention is susceptible to use in a variety of surgical procedures, it is "especially useful in surgical procedures for dividing the transverse carpal ligament (flexor retinaculum) in order to decompress the median nerve in the carpal tunnel," *i.e.*, endoscopic carpal tunnel release surgery. *Id.* at col. 3, ll.

31-38. A graphical representation of the patented device, and specifically a side elevational cut-away view of one embodiment of its surgical probe, is set forth below. *Id*. at col. 2, ll. 36-37.

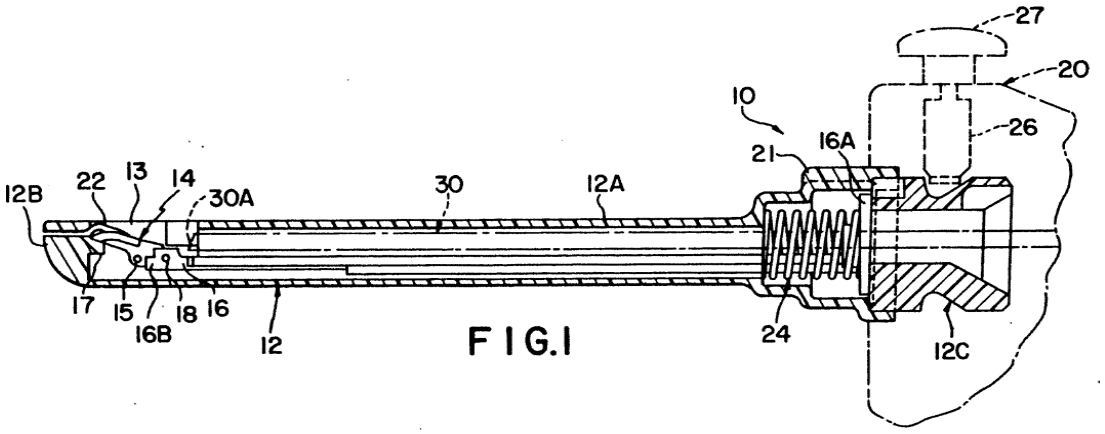


FIG.1

The general operation of the surgical instrument claimed in the '284 Patent can be described in the following manner. The distal or forward end of this probe, identified as **12B** in Figure 1, is inserted into the body cavity of the wrist of the patient undergoing endoscopic carpal tunnel release surgery, and this end is shaped so as to divert displaceable tissue it contacts away from the upper surface and lateral aperture, identified as **13**, of said probe. *Id*. at col. 3, ll. 45-57. The cutting blade, identified as **14**, is shown above in its retracted position, and so does not come into contact with body tissue when the instrument is inserted into the body cavity. The surgeon operating this instrument, by way of the optical viewing scope identified as **30** connected to a conventional video monitor (not shown) can position the probe precisely where desired before extending said cutting blade. *Id*. at col. 4, ll. 12-22. The probe housing and actuator arm **16** of this instrument are preferably made of durable plastic so it is economically disposable after use. *Id*. at col. 9, ll. 3-5.

In the "Background of the Invention" section of the '284 Patent, incorporated by reference are several previously-issued patents, or prior art, United States Patent Nos. 4,962,770, 5,089,000, and particularly 4,963,147 ("the '147 Patent"), which describe an older model of surgical instrument

used in endoscopic carpal tunnel release surgery. ‘284 Patent, col. 1, ll. 11-15. Both instruments were invented by John M. Agee and Francis King, although several additional persons were listed as inventors, and 3M listed as an additional assignee, of the ‘284 Patent. After this previous invention was inserted into the body cavity in the wrist during surgery, “the cutting blade is extended through a lateral aperture in the probe to a position adjacent the selected tissue.” *Id*. at col. 1, ll. 16-19. When the cutting blade in that previous invention so extended, “the distal portion of the blade sweeps through an arc to reach a fully extended position. Initially the distal tip of the blade moves toward the distal end of the probe and then moves upwardly to its fully extended position.” *Id*. at col. 1, ll. 24-28. The ‘284 Patent concludes its description of the previous invention by stating that “[t]his forward movement of the tip of the blade can be undesirable because the tip of the blade can encounter tissue which is not intended to be cut,” and further, the “tip of the blade is not easily visible as it is being elevated.” *Id*. at col. 1, ll. 28-32.

The trajectory of the cutting blade in the previous invention is depicted in Figures 8 and 10 of the ‘147 Patent. Figure 8 depicts a fragmentary view of the previous invention, showing the probe during extension of a cutting blade, and Figure 10 depicts an enlarged sectional view of the distal end of the probe, with the longitudinal axis of a cutting blade shown in positions respective to the actuation of the working tool extension shaft. ‘147 Patent, col. 4, ll. 21-22, 26-30.

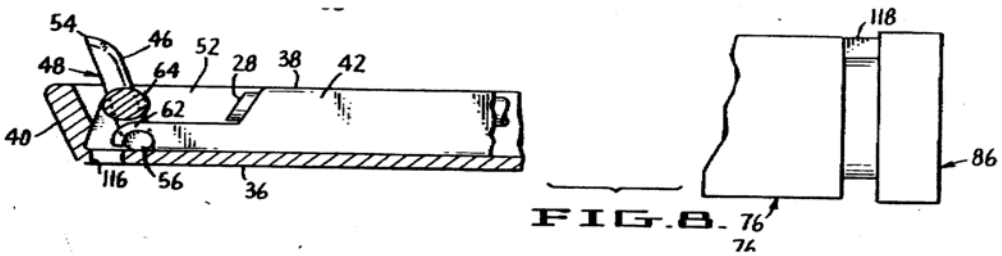


FIG. 8

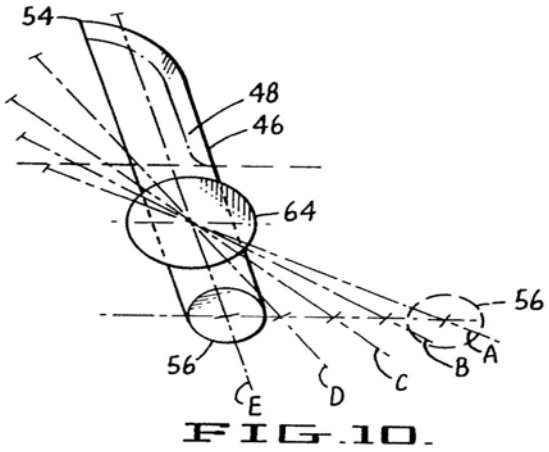


FIG. 10.

The specification of the '147 Patent recites that in Figure 10, one can see the extension of the blade member "rotating through an arc into a fully extended position." *Id*. at col. 7, ll. 1-7. Blade angle B in Figure 10 represents where "the point **54** and cutting blade **46** of blade member **48** project through lateral aperture **50** and above the boundary of upper surface **38** of probe **26**." *Id*. at col. 7, ll. 11-14. Figure 10 corresponding to such language in the specification illustrates continued distal movement of said blade member between blade angle A, where the blade is in its retracted position, and blade angle C. Thereafter, Figure 10 illustrates proximal movement of the blade member (toward the point of origin of the instrument's entry) between blade angle C and the point of full extension in blade angle E.

The '284 Patent contrasts the trajectory of its cutting blade during extension with that illustrated and described above in the '147 Patent. It is the significance of this contrasting language with which the bulk of this Court's opinion is concerned. In the section entitled "Summary of the Present Invention" of the '284 Patent specification, it states that the "present invention" has "provided improved surgical instruments" for this function, namely:

> Means are provided for extending a cutting blade outwardly from the probe in a nearly vertical path. The blade remains within the field-of-view of the optical system at all times. Also, because the tip of the blade does not move distally as it is elevated, it does not encounter

> unintended tissue. Accordingly, use of the surgical instruments of this invention can be very safe, enabling greater control over movement of the blade out of the probe.

'284 Patent, col. 1, ll. 39-47. Those figures in the '284 Patent clearly illustrating[1] its claimed blade elevating means (or "actuating means") are depicted below.

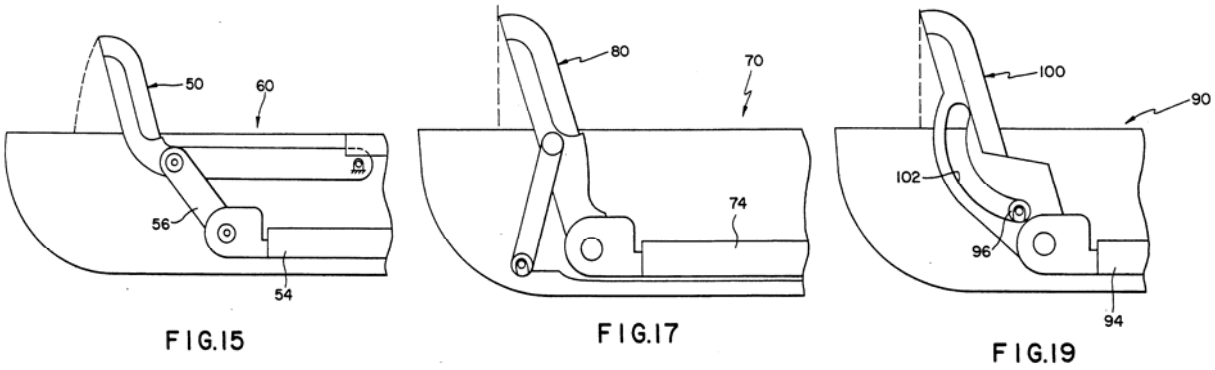


FIG.15 FIG.17 FIG.19

An employee for MicroAire with engineering responsibility for the CTRS instrument was able to examine Arthrex's new Centerline endoscopic carpal tunnel release instrument at a September 2009 meeting of the American Society for Surgery of the Hand. Declaration of Kenneth M. Welborn of Nov. 30, 2009, at ¶ 6 (docket no. 7, ex. D) (hereinafter "First Welborn Declaration"). The Arthrex booth at this meeting was manned by Thomas Aust, previously an employee of Colson Europe B.V. (a MicroAire sister company) who had been involved with MicroAire's CTRS product in Europe. *Id*. After inspection of Arthrex's Centerline instrument, the MicroAire employee concluded that it was "positioned to be a direct substitute for MicroAire's CTRS instrument." *Id*. at ¶ 7. MicroAire argues that based upon the Welborn Declaration, it is apparent that Arthrex's Centerline instrument possesses each and every one of the features claimed in Claim 37 of the '284

[1] The Court finds *infra* that Figures 12 and 13 also depict the '284 Patent's blade elevating means. However, as those figures illustrate the probe in its entirety and do not clearly indicate the blade's trajectory upon extension, they are not reproduced here.

Patent.[2] MicroAire's Memorandum in Support, at 13-14. In the instant proceedings, Arthrex only disputes whether the Centerline instrument has the features claimed in limitation (d) of Claim 37, which claims "actuating means for extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing." Arthrex's Opposition, at 11-16 (citing '284 Patent, col. 14, ll. 57-61).

Subsequently, MicroAire came to the conclusion that Arthrex's Centerline instrument infringed at least upon Claim 37 of the '284 Patent, and contacted Arthrex by letter. When MicroAire failed to receive a "substantive response" after six weeks, MicroAire filed suit alleging patent infringement and related torts under Virginia law. MicroAire now moves the Court for a preliminary injunction "to prohibit [Arthrex] from making, using or selling an infringing carpal tunnel release instrument." MicroAire's Memorandum in Support, at 2.

II. APPLICABLE LAW

The Court has jurisdiction over the instant action as it is one arising under an "Act of Congress relating to patents." 28 U.S.C. § 1338(a); *McCook Metals LLC v. Alcoa, Inc.*, 249 F.3d 330, 333 (4th Cir. 2001) (noting that Section 1338 "confers original jurisdiction over patent-related claims on district courts").

Pursuant to 35 U.S.C. § 283, this Court "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." The purpose of a preliminary injunction "is to protect the status quo and to prevent irreparable harm during the pendency of a lawsuit ultimately to preserve the court's ability

[2] Claim 37 in its entirety is set forth, *infra*, in Section III(A).

to render a meaningful judgment on the merits." *In re Microsoft Corp. Antitrust Litig.*, 333 F.3d 517, 525 (4th Cir. 2003). In the patent context, a preliminary injunction has a similarly conservatory function. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344-45 (Fed. Cir. 2008) (stating that at the preliminary injunction stage, "before the issues of fact and law have been fully explored and finally resolved, the purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held") (internal quotation marks omitted).

The Court applies the standard set forth by the Supreme Court in *Winter v. Natural Resources Defense Council* in determining whether preliminary injunctive relief is appropriate. --- U.S. ----, 129 S.Ct. 365, 172 L.E.2d 249 (2008). The Fourth Circuit recently recognized that *Winter* was in "fatal tension" with circuit precedent governing the grant or denial of preliminary injunctions as articulated in *Blackwelder Furniture Co. of Statesville v. Seilig Mfg. Co.*, 550 F.2d 189 (4th Cir. 1977), and therefore expressly adopted the *Winter* standard. *Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342, 345-47 (4th Cir. 2009); *see also Holbrook v. University of Virginia*, --- F.Supp.2d ----, 2010 WL 1417807, at *2 (W.D. Va. 2010) ("In place of *Blackwelder*, the Fourth Circuit has adopted the four-prong test articulated in *Winter*."). This standard similarly governs the issuance of a preliminary injunction in the context of a suit by the patentee against an alleged infringer for patent infringement. *See e.g.*, *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375-76 (Fed. Cir. 2009) (applying the *Winter* factors, which the court characterizes as being of "longstanding and universal applicability"); *PRE Holding, Inc. v. Monaghan Med. Corp.*, No. 3:09-cv-458, 2009 WL 3874171, at *1 (E.D. Va. Nov. 19, 2009) (stating, with regard to a motion for preliminary injunctive relief in a patent infringement suit, that "[o]bviously, [the *Winter*] standard governs the case at hand"). Consistent with the application of the *Winter* standard, the law of the Federal Circuit further governs the issuance of a preliminary injunction in patent cases. *Hybritech*,

Inc. v. Abbott Labs., 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988); *Mike's Train House, Inc. v. Broadway Ltd. Imports, LLC*, --- F.Supp.2d ----, 2010 WL 1731677, at *2 (D.Md. Apr. 29, 2010). However, for those "procedural issues not affecting substantive patent law principles, . . . the law of the regional circuit where the case was tried," which is that of the Fourth Circuit, is the governing law. *In re Cygnus Telecomm. Tech., LLC, Patent Litig.*, 536 F.3d 1343, 1351-52 (Fed. Cir. 2008); *see also Reynolds & Reynolds Holdings, Inc. v. Data Supplies, Inc.*, 301 F.Supp.2d 545, 549 (E.D. Va. 2004) (noting that in patent cases filed in Virginia, "Federal Circuit law governs substantive issues, and the law of the Fourth Circuit applies to procedural matters that are not unique to patent law").

To obtain a preliminary injunction, the plaintiff "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter,* 129 S.Ct. at 374. A preliminary injunction is "an extraordinary remedy never awarded as of right," *id.* at 376 (citing *Munaf v. Geren*, 553 U.S. 674, 128 S.Ct. 2207, 2219 (2008)), and it "involve[es] the exercise of very far-reaching power to be granted only sparingly and in limited circumstances." *Microstrategy Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001) (citing *Direx Israel Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 816 (4th Cir. 1991)); *see also Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) (citing *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993)) ("A preliminary injunction is a 'drastic and extraordinary remedy that is not to be routinely granted."). The movant has the burden of showing entitlement to a preliminary injunction. *See Reebok Intern., Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994) (citing *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 388 (Fed. Cir. 1987)). While the Court must weigh all the aforementioned factors, *Sofamor Danek Group, Inc. v.*

DePuy-Motech, Inc., 74 F.3d 1216, 1219 (Fed. Cir. 1996), the first two factors in this inquiry (*i.e.*, the likelihood of success and irreparable harm factors) are "[c]entral to the movant's burden," and the Court "may decline to issue a preliminary injunction if the movant does not prove either of these factors." *Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1380 (Fed. Cir. 2000); *see also Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 141 F.3d 1084, 1088 (Fed. Cir. 1998) (holding that the movant "had to establish *both* of the first two factors, *i.e.*, likelihood of success and irreparable harm, to receive a preliminary injunction").

The Court will address each of the above-cited factors required pursuant to *Winter* for the issuance of a preliminary injunction, in turn.

III. DISCUSSION

A. LIKELIHOOD OF SUCCESS ON THE MERITS

First, as the movant for a preliminary injunction, MicroAire must establish that it is "likely to succeed on the merits." *Winter*, 129 S.Ct. at 374. In a patent infringement case, this means that MicroAire must show, in light of the presumptions and burdens that will inhere at trial on the merits, that: (1) MicroAire, as the patentee, will likely prove that its competitor, Arthrex, infringes upon the '284 Patent; and (2) MicroAire's infringement claim will likely withstand Arthrex's challenges to the validity and enforceability of the '284 Patent. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *see also Erico Intern. Corp. v. Vutec Corp.*, 516 F.3d 1350, 1354 (Fed. Cir. 2008) (stating that to meet this factor, the patentee "must show a likelihood that [the defendant] infringes a valid claim" of the patent, while the defendant "must show a substantial question of invalidity to avoid a showing of likelihood of success"). MicroAire need only show that one claim to the '284 Patent has been infringed to establish that it is likely to succeed on

the merits. *See Panduit Corp. v. Dennison Mfg. Co., Inc.*, 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987) ("One is liable for patent infringement if one claim be infringed.").

The Court's determination on the likelihood of infringement involves a two-step analysis. At step one, claim construction, the Court assesses the scope and meaning of the patent claims asserted. *Oakley, Inc. v. Sunglasses Hut Intern.*, 316 F.3d 1331, 1339 (Fed. Cir. 2003) (citing *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc)). At step two, the Court compares the construed patent claims to the allegedly infringing device, and must find that every claim limitation, or its equivalent, is found in the accused device. *Oakley, Inc.*, 316 F.3d at 1339 (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 117 S.Ct. 1040 (1997)). To prove literal infringement, MicroAire must show "that the accused device contains each limitation of the asserted claim." *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 812 (Fed. Cir. 2002). If MicroAire is unable to prove literal infringement, "a product or process . . . may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention," *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1367 (Fed. Cir. 2007), that is, if MicroAire can show "that the accused device contains an equivalent for each limitation not literally satisfied," *Dawn Equip. Co. v. Kentucky Farms*, 140 F.3d 1009, 1015 (Fed. Cir. 1998). Claim construction is a question of law, *Cybor*, 138 F.3d at 1456, whereas the Court's comparison of the patent claims to the allegedly infringing device is a question of fact. *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 906 (Fed. Cir. 2005).

MicroAire argues that Arthrex's Centerline carpal tunnel release instrument specifically infringes Claim 37 of the '284 Patent, which covers the following:

37. A disposable probe for use in a surgical instrument for manipulating selected tissue in a body cavity under visual observation, said probe comprising:

(a) an elongated tubular housing having proximal and distal ends; wherein said distal end is generally closed; wherein said housing includes an upper surface having a lateral aperture in said upper surface adjacent said closed distal end; wherein said distal end slopes away from said upper surface in a manner such that said distal end diverts displaceable tissue it contacts away from the region of said lateral aperture and said upper surface;
(b) an elongated cavity extending longitudinally through said housing for accepting an optical system;
(c) a working tool comprising a blade means mounted within the housing adjacent said lateral aperture and including a cutting blade capable of dividing selected tissue; wherein said cutting blade includes a distal end portion;
(d) actuating means for extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing.

'284 Patent, col. 14, ll. 37-61.

The parties dispute the proper construction of limitation (d) of Claim 37 of the '284 Patent. The proposed constructions of this phrase by MicroAire and Arthrex are set forth below.

MICROAIRE'S PROPOSED CONSTRUCTION		ARTHREX'S PROPOSED CONSTRUCTION
Claim 37, Limitation (d): "actuating means for extending said cutting blade outwardly from said probe in a manner such that said portion away from the point of origin of said cutting blade follows a path which meets the lengthwise axis of said housing at what is in essence a right angle."		*Claim 37, Limitation (d)*: "in a manner such that the tip of the cutting blade follows a path which necessarily forms a right angle with the longitudinal axis of said housing and does not move distally (forward) relative to the probe during elevation."

1. General Claim Construction Principles

The patentee may exercise the right to exclude, and "the *claims* of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (emphasis added). The patentee must "define precisely what

his invention is," because it would be "unjust to the public, as well as an evasion of the law, to construe [the patent] in a manner different from the plain import of its terms." *Id*. (quoting *White v. Dunbar*, 119 U.S. 47, 52, 7 S.Ct. 72 (1886)).

Therefore, the Court begins its claims construction analysis with the words of the claim. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The words of a claim are given their ordinary and customary meaning, which "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1142 (Fed. Cir. 2005) (citing *Phillips*, 415 F.3d at 1313). This person of ordinary skill in the art is not deemed to read the disputed claim term in isolation, but instead "views the claim term in light of the entire intrinsic record," *Nystrom*, 424 F.3d at 1142, *i.e.*, "in the context of the entire patent, including the specification." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1357 (Fed. Cir. 2006) (quoting *Phillips*, 415 F.3d at 1313). The specification is required to provide a written description of the invention in "full, clear, concise, and exact terms," 35 U.S.C. § 112, and the patentee may satisfy this requirement by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1159, 1566 (Fed. Cir. 1997). On questions of claim construction, "[u]sually, [the specification] is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (citing *Vitronics*, 90 F.3d at 1582).

The following principles of claim construction are of particular importance to the instant case: (1) where the specification "may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess," it is "the inventor's lexicography" that governs, *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)); and (2) where the specification "may reveal an intentional

disclaimer, or disavowal, of claim scope by the inventor," again, "the inventor's intention, as expressed in the specification, is regarded as dispositive, *id*. at 1316 (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001)).

Next, the patent's prosecution history, as part of the "intrinsic record," should also be considered by the Court when construing a claim. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc). This consists of the complete record of proceedings before the Patent and Trademark Office, and includes prior art cited in the patent examination. *Phillips*, 415 F.3d at 1317. The patent prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes," *id.*, however, it is still "often of critical significance in determining the meaning of the claims." *Vitronics*, 90 F.3d at 1582.

Generally, the Court will be able to resolve any ambiguity in a disputed claim term by considering the intrinsic record, in which case, "it is improper to rely upon extrinsic evidence." *Vitronics*, 90 F.3d at 1583; *see also Pickholtz v. Rainbow Techs., Inc.*, 284 F.3d 1365, 1372-73 (Fed. Cir. 2002) ("Only if a disputed claim term remains ambiguous after analysis of the intrinsic evidence should the court rely on extrinsic evidence."). Dictionaries, treatises, and other types of extrinsic evidence, while considered to be "less reliable than the patent and its prosecution history in determining how to read claim terms," *Phillips*, 415 F.3d at 1318, are still "an available resource" and are "often useful" to claim construction. *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000).

2. Means-Plus-Function Limitation

The first question the Court must address is whether limitation (d) of Claim 37 can be accurately characterized as a means-plus-function limitation, which would invoke the provisions of

35 U.S.C. § 112, ¶ 6.[3] A means-plus-function limitation is one which allows the patentee "to recite a function to be performed as a claim limitation rather than reciting structure or materials for performing the function." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1321 (Fed. Cir. 2003). Whether limitation (d) of Claim 37 falls within the strictures of § 112, ¶ 6 is of critical importance to the Court's claim construction analysis.[4] Section 112, ¶ 6 "operates to restrict claim limitations drafted in such functional language to those structures, materials or acts disclosed in the specification (and their equivalents) that perform the claimed function." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998); *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002) ("A claim using that format will cover only the corresponding step or structure disclosed in the written description, as well as that step or structure's equivalents."). Where a limitation is not governed by § 112, ¶ 6, "this court construes the claims with standard claim construction rules. Thus, for instance, the specification informs but does not control, the claim construction." *Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360, 1365 (Fed. Cir. 2000).

MicroAire argues that limitation (d) of Claim 37 is in means-plus-function form. First, it asserts that the "actuating means used in [Arthrex's] Centerline product is 'is [sic] virtually identical to the mechanism shown in Figures 18 and 19 of U.S. Patent No. 5,306,284." MicroAire has found no reported case "applying the doctrine of prosecution disclaimer," as Arthrex attempts to do, "to a

[3] "An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6.

[4] The claim construction inquiry for a means-plus-function limitation "is fundamentally different, and employs very different paradigms to translate the language of the claim into an understanding of technical scope," from the Court's usual inquiry. 1 *Moy's Walker on Patents* § 4:89 (4th ed. 2004). First, the Court "must identify the claimed function . . . staying true to the claim language and the limitations expressly recited by the claims." *Omega Eng'g*, 334 F.3d at 1321. Second, the Court "must then ascertain the corresponding structures in the written description that perform these functions." *Id*.

case of literal infringement of a means-plus-function claim where . . . the accused device employs a structure expressly disclosed in the specification of the patent in question." MicroAire's Reply Brief, at 6. Accordingly, MicroAire concludes that there has not been any prosecution disclaimer, because this doctrine requires disclaimer to be unambiguous. Second, it asserts that Arthrex's proposed claim construction should be rejected because it allegedly construes limitation (d) in a manner that ignores the key term "actuating means." MicroAire's Reply Brief, at 8. After providing a definition for the means-plus-function form, MicroAire states that the specification of the '284 Patent "describes four structures by which the function of the 'actuating means … ' may be performed," found in Figures 12 – 19, and in the figures' accompanying descriptions. MicroAire's Reply Brief, at 8-9. As Arthrex has allegedly excluded the structures shown in Figures 18 and 19 in its proposed claim construction, MicroAire argues that such a construction should be rejected. MicroAire's Reply Brief, at 9.

The use of the word "means" "triggers a presumption that the inventor used this term advisedly to invoke the statutory mandate for means-plus-function clauses." *Allen Eng'g Corp. v. Bartrell Indus. Inc.*, 229 F.3d 1336, 1347 (Fed. Cir. 2002) (quoting *York Prods., Inc. v. Cent. Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1574 (Fed. Cir. 1996)). Limitation (d) of Claim 37 is therefore presumed to be a means-plus-function clause and fall within § 112, ¶ 6, because it uses the words, "actuating *means for* extending said cutting blade outwardly[.]" (Emphasis added). However, the inventor's use of the word "means" does not conclude the Court's inquiry. The presumption may be overcome either where a claim element "uses the word 'means' but recites no function corresponding to the means," or, importantly in the instant case, where "the claim element specifies a function," but "it also recites sufficient structure or material for performing that function." *Allen Eng'g*, 299 F.3d at 1347. Therefore, the use of the word 'means' will not transform every limitation into a means-plus-function limitation. *See Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed.

Cir. 1996).

Claim 37, limitation (d), provides for "actuating means for extending said cutting blade outwardly from said probe in a manner such that said distal portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing." In this case, the patentee has not recited sufficient structure to overcome the presumption that it is a means-plus-function limitation. While there is some specificity in limitation (d) concerning the *trajectory* of the cutting blade's extension from the housing, and the location from which the cutting blade is to be extended, there is no structural description of the "actuating means" itself contained within the claim. Sufficient description of the structure of the "means" is required to overcome the means-plus-function presumption. *Compare TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., LLC.*, 375 F.3d 1126, 1135 (Fed. Cir. 2004) (means-plus-function presumption overcome where claim limitation for "pumping means" recited its structure, "a nozzle and a venturi tube in alignment with the nozzle," location, "being located within the reservoir in the region of the opening," and method of operation); *Searfoss v. Pioneer Consol. Corp.*, 374 F.3d 1142, 1149 (Fed. Cir. 2004) (means-plus-function presumption overcome where claim limitation specifically set forth the structure that performs the claimed function, by reciting "said actuation means including first and second pivot connections respectively between said first and second tension bail legs and a midpoint on said respective first and second extension bail legs"), *with Omega Eng'g*, 334 F.3d at 1321 (holding that claim was in means-plus-function format where it recited "means for causing said at least one laser beam to strike the periphery of the energy zone for visibly outlining said entire energy zone"). The Court finds that limitation (d) of Claim 37 does not contain adequate recitation of the structure of "actuating means" to overcome the presumption that it is in means-plus-function format, and, there being no arguments presented by the parties to the contrary, the Court concludes that this is a means-

plus-function limitation, governed by 35 U.S.C. § 112, ¶ 6.

3. Means-Plus-Function Claim Construction

Having concluded that the contested limitation is in means-plus-function format, the Court engages in a unique two-step claim construction analysis, informed, of course, by the aforementioned general principles of claim construction. With this type of claim limitation, the Court first "must identify the claimed function . . . staying true to the claim language and the limitations expressly recited by the claims." *Omega Eng'g*, 334 F.3d at 1321. When the Court construes the functional statement in a means-plus-function limitation, it "must take great care not to impermissibly limit the function by adopting a function different from that explicitly recited in the claim." *Generation II Orthotics, Inc. v. Med. Tech., Inc.*, 263 F.3d 1356, 1364-65 (Fed. Cir. 2001). "Ordinary principles of claim construction govern interpretation of the claim language used to describe the function." *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002). The second step in this claim construction analysis is for the Court to "ascertain the corresponding structures in the written description that perform those functions." *Omega Eng'g*, 334 F.3d at 1321 (citing *St. Jude Med.*, 296 F.3d at 1113). A disclosed structure is defined as corresponding "only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim." *Omega Eng'g*, 334 F.3d at 1321 (quoting *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)).

i. Parties' Contentions

The Court notes at the outset of its claim construction inquiry that the parties do not appear to be in complete agreement regarding which claim terms are in dispute. Both parties have submitted proposed constructions concerning Claim 37, limitation (d). However, MicroAire argues that the claim term specifically in dispute is "actuating means," and it proceeds to state that Arthrex's

competing proposed construction of Claim 37 "omits" and "ignores" "the critical language 'actuating means' for extending said cutting blade outwardly from said probe . . . ." MicroAire's Reply, at 6, 8. By contrast, Arthrex focuses its energies in its claim construction arguments upon the proper construction of the term "essentially perpendicular." Arthrex's Opposition, at 10-13. Indeed, as MicroAire suggested, Arthrex does not even include the language "actuating means for extending said cutting blade outwardly from said probe" in its proposed claim construction. Arthrex's Opposition, at 11. Accordingly, in the event that there is disagreement between the parties as to which claim terms are in dispute, the Court will construe the terms "essentially perpendicular" and "actuating means" found in Claim 37.

Arthrex contends that a proper construction of limitation (d), which claims "actuating means for extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing," should contain the additional limitations that "the cutting blade follows a path which necessarily forms a right angle with the longitudinal axis of said housing and does not move distally (forward) relative to the probe during elevation." Arthrex's Opposition, at 11. According to Arthrex, the prosecution history of the '284 Patent compels this construction of the term, "essentially perpendicular." Arthrex contends that the patentee has "unequivocally disavowed a certain meaning to obtain his patent," and therefore, "the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim." Arthrex's Opposition, at 8.

In support of its proposed claim construction, Arthrex makes reference to the specification and prosecution history of the '284 Patent. *See* Arthrex's Opposition, at 4-6, 11-12. Specifically, Arthrex cites the fact that when the patent examiner conducted a prior art search of Original Claim 49 (now Claim 37), it was rejected under 35 U.S.C. § 102(b) because the examiner found the claim

"as being clearly anticipated by Agee et al '147," which was the patentee's previous Patent '147. Arthrex's Opposition, at 5. In response to this rejection, Arthrex argues that the patentee sought to define the claimed invention over the '147 Patent. The patentee allegedly attempted to narrow the definition of "essentially perpendicular," by stating that "the instrument of the present invention provides for elevation of the cutting blade along a path which is essentially perpendicular to the longitudinal axis of the probe. *In other words, in the present invention the tip of the cutting blade does not move distally* [*toward the tip of the probe*] *relative to the probe during elevation*." Arthrex's Opposition, at 5, 11-12 (citing Applicant's Amendment of Apr. 23, 1993 (docket no. 7, ex. E9, at 22)) (hereinafter "Applicant's Amendment") (emphasis added). Arthrex contends that in reliance upon this distinction, the patent examiner allowed the application to be issued as the '284 Patent. Arthrex's Opposition, at 6 (citing Notice of Allowability of Aug. 10, 1993 (docket no. 7, ex. E19)) (hereinafter "Notice of Allowability"). Therefore, Arthrex concludes that a proper construction of "essentially perpendicular" in Claim 37 is one which "necessarily forms a right angle with the longitudinal axis of said housing and does not move distally (forward) relative to the probe during elevation." Arthrex's Opposition, at 11.

In reply, MicroAire argues first that there has been no prosecution disclaimer in this case, as, in effect, Arthrex has been unable to show a disavowing statement by the patentee that is "so clear as to show reasonable clarity and deliberateness." MicroAire's Reply, at 3 (citing *University of Pittsburgh v. Hendrick*, 573 F.3d 1290, 1296 (Fed. Cir. 2009)). Specifically, MicroAire points to the fact that the language of Original Claim 49 (now Claim 37) was not amended or withdrawn in response to the patent examiner's rejection. MicroAire's Reply, at 5. The remarks identified by Arthrex in the prosecution history are alleged not to have any significance beyond a mere explanation of differences between the previous '147 Patent and the '284 Patent, which had had

been set forth already in the Application for said Patent. MicroAire's Reply, at 6 (citing Application for Patent of Feb. 19, 1992, at 1-2 (docket no. 7, ex. E1) (hereinafter "Patent Application"). Furthermore, MicroAire argues that the "actuating means used in [Arthrex's] Centerline product is virtually identical to the mechanism shown in Figures 18 and 19" of the '284 Patent." MicroAire's Reply, at 7. It contends that the doctrine of prosecution disclaimer does not apply where the allegedly infringing product is "virtually identical" to a figure in the patent, as such figures, and their descriptions, are expressly incorporated into the claim term where said term is in means-plus-function format. MicroAire's Reply, at 7. Accordingly, MicroAire argues that Arthrex's proposed claim construction should be rejected because it excludes the structure shown in Figures 18 and 19, and therefore "fails to comport with" the requirements of § 112, ¶6 of the Patent Act. MicroAire's Reply, at 9.

ii. The Claimed Function: Distal Movement

After consideration of the parties' contentions and in accordance with the aforementioned principles of claim construction, the Court finds that the claimed function of the disputed term, "actuating means" is for "extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing, *and does not move distally relative to the probe during elevation*."

In reaching this conclusion, the Court has taken heed of the cautionary language of the Federal Circuit that this Court "must take great care not to impermissibly limit the function by adopting a function different from that expressly recited in the claim." *Omega Eng'g,* 334 F.3d at 1322 (citing *Generation II Orthotics*, 263 F.3d at 1364-65). In a similar vein, the Court recognizes that "[c]laim terms are entitled to a 'heavy presumption' that they carry their ordinary and customary

meaning to those skilled in the art in light of the claim term's usage in the patent specification." *Elbex Video, Ltd. v. Sensormatic Electronics Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007) (applying this presumption to construction of the claimed function of a means-plus-function limitation).

The Court's construction of the functional statement of Claim 37 is compelled by the doctrine of prosecution disclaimer, as well as by the express language in the specification and the figures of the '284 Patent, which are incorporated into this means-plus-function claim.

The Court is to "indulge" this "heavy presumption" that the claim terms carry their ordinary and customary meaning "unless the patentee unequivocally imparted a novel meaning to those terms or *expressly relinquished claim scope during prosecution*." *Omega Eng'g*, 334 F.3d at 1323 (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325-26 (Fed. Cir. 2002)) (emphasis added); *see also Cybor Corp.*, 138 F.3d at 1457 (stating that a patent's prosecution history "is relevant to the construction of a claim written in means-plus-function form"). The doctrine of prosecution disclaimer is "well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution," and accordingly, the Federal Circuit "adopted that doctrine as a fundamental precept in [its] claim construction jurisprudence." *Id*. (collecting cases). Prosecution disclaimer attaches and narrows the ordinary meaning of a claim, congruent with the scope of surrender, where the patentee has unambiguously disavowed a certain meaning of said claim to obtain his patent. *See e.g., Elbex Video*, 508 F.3d at 1371; *Omega Eng'g*, 334 F.3d at 1324.

The prosecution history of the '284 Patent is replete with indicia that the patentee intended to disavow any claim to "actuating means . . . " that functioned to extend the cutting blade outwardly from the probe *in a manner that moved distally relative to the probe during elevation*. In the Application for this Patent, the applicant clearly distinguished the present invention from the prior

‘147 Patent on this very ground, by using the following language in the specification.

> Background of the Invention
>
> U.S. Patents 4,963,147 . . . incorporated herein by reference, describe[s] a surgical instrument which is very useful in techniques for carpal tunnel release[.] . . .
>
> In the surgical instrument just described the cutting blade extends through an axially fixed rotatable pivot pin. As an actuation shaft urges the cutting blade through the pivot pin, *the distal end portion of the blade sweeps through an arc to reach a fully extended position. Initially the distal tip of the blade moves toward the distal end of the probe and then moves upwardly to its fully extended position. This forward movement of the tip of the blade can be undesirable because the tip can encounter tissue which is not intended to be cut*. Also, the tip of the blade is not easily visible as it is being elevated.
>
> Summary of the Present Invention
>
> In accordance with the present invention there are provided improved surgical instruments for manipulating selected tissue in a body cavity under visual inspection. The instruments comprise blade means mounted within an elongated probe. Means are provided for extending a cutting blade outwardly from the probe in a nearly vertical path. The blade remains within the field-of-view of the optical system at all times. *Also, because the tip of the blade does not move distally as it is elevated, it does not encounter unintended tissue*. Accordingly, use of the surgical instruments of this invention can be very safe, enabling greater control over movement of the blade out of the probe.

Patent Application, p. 1, ll. 7-10, 17-36, p. 2, ll. 1-4 (emphasis added).

In the Application, the language of Original Claim 49 (now Claim 37) similarly provided for “actuating means for extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing.” Patent Application, cl. 49, ll. 20-24. As the Court has concluded *infra*, in Section III(A)(2), that identical language in the ‘284 Patent constitutes a means-plus-function limitation, so too would Original Claim 49 of the Application have incorporated the above-

cited language distinguishing the prior art. *See* 35 U.S.C. § 112, ¶ 6 (stating that means-plus-function limitations "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof").

Pursuant to 35 U.S.C. § 102(b),[5] the patent examiner rejected Original Claim 49, among others, as being "clearly anticipated by Agee et al '147," which was the applicant's previous '147 Patent. In response thereto, the applicant sought to amend the Application, and specifically with respect to the rejection of Original Claim 49 (now Claim 37), the applicant argued as follows:

> The claims in issue include the recitation that the cutting blade is extended outwardly from the probe in a manner such that the distal end portion of the cutting blade "follows a path which is essentially perpendicular to the longitudinal axis of the probe". This feature is not described or shown in the cited reference relied upon by the Examiner. As is apparent from Figures 7 and 8 of the cited references (Agee '147), the blade 48 is attached at its proximal end to shaft 42, and the blade extends through the slot in pivot 64. In order to elevate the blade, the shaft 42 is urged toward the distal end of the probe. *This causes the blade to move through the slot in the pivot in a distal direction. Then with continued movement of the shaft 42 the blade begins to move upwardly. Thus, the tip of the blade passes through an arc in order to reach its fully-elevated position shown in Figure 8. Because the pivot 64 is in a stationary position relative to the axis of the probe, movement of the shaft 42 toward the distal end of the probe necessarily causes the tip of the blade to initially move in a distal direction relative to the probe before the blade proceeds to its fully-elevated position.*
>
> *In contrast to that operation, the instrument of the present invention provides for elevation of the cutting blade along a path which is essentially perpendicular to the longitudinal axis of the probe. In other words, in the present invention the tip of the cutting blade does not move distally relative to the probe during elevation. This is very significant because it enables the surgeon to accurately position the probe in a body cavity so that when the blade is elevated it is located precisely where it is needed. If the tip of the blade extends distally relative to the probe when it is being elevated, it could inadvertently*

[5] "A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b).

> *contact body tissue which is not desired to be cut.*
>
> In view of the foregoing, the Section 102 rejection is unsound and should be withdrawn. The cited reference does not describe every feature of the claims in issue.

Applicant's Amendment, at 22-23 (emphasis added). Thereafter, on August 10, 1993, the patent examiner issued a "Notice of Allowability," which was "responsive to" the Applicant's Amendment, and which held all the claims to be allowable and closed patent prosecution.

The aforementioned language cited in the Patent Application was thus included in the specification of the '284 Patent, without amendment. '284 Patent, col. 1, ll. 10-14, 21-47. Similarly, the language of Claim 37 was included in the '284 Patent from Original Claim 49 of the Patent Application, without amendment. '284 Patent, col. 14, ll. 37-61. Furthermore, the specification of the '284 Patent recites that "[o]ther embodiments of surgical instruments are also provided in which the blade is elevated from the probe *in a manner such that the tip of the blade does not move distally relative to the probe.*" *Id*., col. 2, ll. 15-18 (emphasis added).

The inescapable conclusion from the prosecution history of the '284 Patent, and specifically with reference to the cited portions of the Patent Application, the Amendment, and ultimately the specification and figures of the '284 Patent, is that the patentee unambiguously and unequivocally disavowed any claim to "actuating means . . ." by which the cutting blade followed a trajectory which moved distally relative to the probe.

The Court finds that the substantial weight of authority supports this conclusion. The rule is that "explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim." *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed. Cir. 1998) (citing *Southwall Techs. Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995)). This is because, "[b]y distinguishing the claimed invention over

the prior art, an applicant is indicating what the claims do not cover." *Id*. at 1378-79 (citing *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997)). The public has a right to rely upon such definitive statements made by the applicant during patent prosecution. *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1347 (Fed. Cir. 1998).

In particular, the Court finds the *Signtech v. Vutek* case in the Federal Circuit to be highly relevant to the present circumstances. *See Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352 (Fed. Cir. 1999). In that case, Signtech sued Vutek for infringement of United States Patent No. 5,376,957 ("the '957 Patent"), which relates to inkjet printers for printing large signs. The '957 Patent disclosed an inkjet printer with an improved ink sprayhead design, namely in that it printed an image and its mirror image on opposite sides of a substrate. To accomplish this, the claimed design of the '957 Patent featured two air sources: "one pressurized air source to control ink delivery onto the substrate and a second low-volume, high pressure air source to continuously clean the ink nozzle during printing." *Id*. at 1354. The dual-sided printing process and the dual air source ink sprayhead were novel features of the '957 Patent. The '957 Patent stated that the prior art, and specifically United States Patent No. 4,914,522 ("the '522 Patent"), owned by Vutek, was "incapable of producing an enlarged image having the desired color scheme *because it lacks this second, high pressure air source*." *Id*. (emphasis added) (internal quotation marks omitted). The allegedly infringing printers made by Vutek used ink sprayheads identical to those embodied in the '522 patent, and only contained a single air source. *Id*. at 1355. As in the instant case, the court in *Signtech* was presented with a question of the proper construction of the "ink delivery means" limitation, which the court found was in means-plus-function form. *Id*. at 1356. Also, as in the instant case, the '957 Patent's "background and summary of the invention sections of the specification [ ] describe[d] the improvements of the ink delivery means of this invention over the

prior art (including the accused ink delivery structure of Vutek's '522 patent." *Id*. at 1356-57. The court characterized the ink delivery structure described in the '522 Patent as one which was "explicitly distinguished by the '957 patent." *Id*. at 1357. The *Signtech* court held that: "[b]y choosing means-plus-function language to recite the 'ink delivery means' element, the patentee necessarily restricted the scope of this element to the structure disclosed in the specification and its equivalents. Furthermore, by stating that the accused device was 'incapable' of achieving the desired results of the invention, the patentee expressly excluded it as an equivalent of the disclosed structure." *Id*.

The '284 Patent at issue in this case similarly attempts to distinguish the prior art (and specifically the '147 Patent) by language included in the "Background of the Invention" and "Summary of the Present Invention" sections of the specification, and such language is similarly incorporated into Claim 37, as it is a means-plus-function limitation. The '284 Patent recites a structural difference between the patents as well, which was that in the prior '147 Patent, "[i]nitially the distal tip of the blade moves toward the distal end of the probe and then moves upwardly to its fully extended position," whereas in the '284 Patent, it recited that "[m]eans are provided for extending a cutting blade outwardly from the probe in a nearly vertical path," and that "the tip of the blade does not move distally as it is elevated[.]" '284 Patent, col. 1, ll. 26-28, 39-41, 43-44. This structural difference was not merely superficial, but was characterized by the patentee as "very significant" during patent prosecution in an attempt to secure the '284 Patent. As in *Signtech*, the patentee recited in the patent several ways in which, due to this structural difference, the prior art could not achieve the desired results of the newer invention. First, the '284 Patent focused upon the accuracy with which the blade connects with the desired tissue. Whereas for the older '147 Patent, it was recited that "[t]his forward movement of the tip of the blade can be undesirable because the tip

can encounter tissue which is not intended to be cut," for the '284 Patent, it was recited that "because the tip of the blade does not move distally as it is elevated, it does not encounter unintended tissue," and it "enable[s] greater control over movement of the blade out of the probe." *Id*., col. 1, ll. 28-31, 43-44, 46-47. Second, the '284 Patent focused upon the visibility of the blade to the surgeon upon extension. Whereas for the older '147 Patent, it was recited that "the tip of the blade is not easily visible as it is being elevated," for the '284 Patent, it was recited that "[t]he blade remains within the field-of-view of the optical system at all times." *Id*., col. 1, ll. 31-32, 41-42. As the circumstances under which the court in *Signtech* found that the patentee had explicitly disavowed a prior art structure are very similar to those presently at issue, the Court is particularly guided by this authority in addition to the aforementioned general principles of claim construction.

However, other authorities support the Court's holding that the claimed function of the disputed term, "actuating means" is for "extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing, *and does not move distally relative to the probe during elevation*." In *Ballard Medical Products*, the court was presented with a question of claim construction of a means-plus-function limitation, and specifically whether in the course of patent prosecution, the applicant had disavowed certain structures by characterizing them as falling outside the scope of his invention. *Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1359 (Fed. Cir. 2001). Ballard Medical Products brought suit against the defendants, alleging infringement of multiple claims of two of its patents that related to ventilating and aspirating tracheobronchial catheters. In response, the defendants argued that their allegedly infringing structures fell outside the scope of Ballard's patents based upon an amendment and affidavit offered to the patent examiner during prosecution. Therein, the applicant had claimed, *inter alia*, that "the

prior art valves were 'pressure valves,' while the valve disclosed and claimed in the [ ] application was a 'vacuum valve.'" *Id*. at 1359. The applicant then had recited the structural difference between the prior art pressure valves and his disclosed vacuum valve. Further, he stated the practical significance thereof by claiming that the former "would seal if vacuum pressure were applied to one end of the catheter, but would tend to open or leak if vacuum pressure were applied to the opposite end," whereas for the latter (his vacuum valve mechanism), it "was not affected by pressure through the catheter from either direction." *Id*. at 1360. The court in *Ballard Medical* concluded that the applicant's "statements identifying his invention as a vacuum valve . . . had the effect of disclaiming pressure valves." *Id*. at 1361. The court concluded that "[b]ecause the patentee explicitly represented during prosecution that his claims differed from structures in the prior art, [it] construe[d] the disputed claims to exclude the disclaimed structures," and thereupon upheld the district court's summary judgment of noninfringement. *Id*. at 1363.

In light of these principles, the Court construes the claimed function of the disputed term, "actuating means . . ." is for "extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path which is essentially perpendicular to the longitudinal axis of said housing, *and does not move distally relative to the probe during elevation*."

iii. The Claimed Function: Essentially Perpendicular

The Court will similarly address the second disputed issue of claim construction in the context of the function performed by the "actuating means," namely what Claim 37 means when it recites that the "cutting blade follows a path which is *essentially perpendicular* to the longitudinal axis of said housing." '284 Patent, col. 14, ll. 59-61 (emphasis added). Arthrex proposes a particularly limiting construction of this claim term, which is that the "cutting blade follows a path

which *necessarily forms a right angle* with the longitudinal axis of said housing[.]" Arthrex's Opposition, at 11 (emphasis added). Conversely, MicroAire proposes that the Court construe this disputed claim term to read that the "cutting blade follows a path which meets the lengthwise axis of said housing at *what is in essence a right angle*." MicroAire's Reply, at 8 (emphasis added).

"Ordinary principles of claim construction govern interpretation of the claim language used to describe the function" of a means-plus-function limitation, *St. Jude Med.*, 296 F.3d at 1113, and therefore the Court begins by looking to the words of the claim. *Vitronics Corp.*, 90 F.3d at 1582. These words are given their ordinary and customary meaning. *Nystrom*, 424 F.3d at 1142. The parties do not argue that "perpendicular" should be taken to mean anything other than "meeting a given line or surface at right angles," *Random House Dictionary of the English Language* 1444 (2d ed. 1987) (hereinafter "*Random House*"), but instead contest how strictly that term should be construed in light of its qualifier, "essentially." "Essential," as the adjective form of the adverb, "essentially," is defined either as "1. absolutely necessary; indispensable," which appears to support Arthrex's proposed construction, or "2. pertaining to or constituting the essence of a thing," which appears to support MicroAire's proposed construction. *Random House Dictionary of the English Language* 663 (2d ed. 1987) (hereinafter "*Random House*"). The Court notes that the example given for the first usage of "essential," *i.e.*, "Discipline is *essential* in an army," indicates that usage is more appropriate for the adjective form rather than as an adverb. Other dictionaries cite the latter definition referenced by MicroAire as the predominant usage of the word "essential." *See e.g.*, *Merriam-Webster's Collegiate Dictionary* 396 (10th ed. 1994) (defining "essential" primarily as "of, relating to, or constituting essence," and secondarily as "of the utmost importance").

However, to the extent there remains any ambiguity in the term "essentially perpendicular," dictionary definitions are considered "less reliable than the patent and its prosecution history in

determining how to read claims." *Phillips*, 415 F.3d at 1318. This is true particularly in the context of means-plus-function claims, as they "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Encyclopaedia Britannica, Inc. v. Alpine Electronics, Inc.*, 355 F. App'x 389, 392 (Fed. Cir. 2009) (citing 35 U.S.C. § 112, ¶ 6).

The language of the specification and the figures disclosed in the '284 Patent do not support the construction of the term "essentially perpendicular" proposed by Arthrex, such that the claimed function of the "actuating means . . ." required that "the cutting blade follows a path which *necessarily forms a right angle with* the longitudinal axis of said housing[.]" Of course, in the "Summary of the Present Invention" section of the specification, it recites that "[m]eans are provided for extending a cutting blade outwardly from the probe *in a nearly vertical path*." '284 Patent, col. 1, ll. 39-41 (emphasis added). However, Arthrex seeks to use the language in the specification and the prosecution history to operate as a disclaimer and disavowal of "actuating means" by which the cutting blade would extend in an arced path, and serve to claim only "actuating means" by which the cutting blade "follows a path which necessarily forms a right angle with the longitudinal axis of said housing[.]" Arthrex's Opposition, at 11. As stated previously, prosecution disclaimer narrows the ordinary meaning of a claim congruent with the scope of surrender, but only where the patentee has *unambiguously disavowed* a certain meaning of said claim to obtain his patent. *See e.g.*, *Elbex Video*, 508 F.3d at 1371; *Omega Eng'g*, 334 F.3d at 1324. The Court has previously found, in Section III(A)(3)(ii), *supra*, that the applicant had unambiguously disclaimed "actuating means" by which the cutting blade would move distally relative to the probe during elevation in order to obtain the '284 Patent.

There is no such unambiguous disclaimer with respect to "actuating means" by which the cutting blade would move in path that was in essence a right angle, but which was slightly arced, so

long as said path did not move distally relative to the probe during elevation. Arthrex is unable to support its case of unambiguous disclaimer on this issue in large part due to Figures 14 and 15 of the '284 Patent (Figure 15 reproduced below), and their accompanying descriptions in the specification.

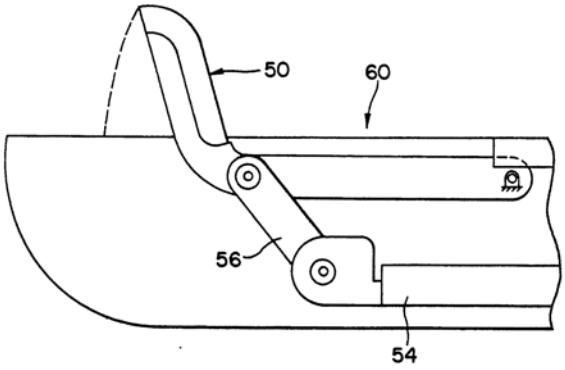


FIG.15

The path of the blade depicted in Figure 15 is one which can be characterized as "essentially perpendicular," but still is a path which does not move distally relative to the probe upon elevation from the lateral aperture in its upper surface. This is further supported in the "Detailed Description of the Invention" section of the specification. The following language is included therein:

> FIGS. **14** and **15** are side elevational views illustrating another manner in which the cutting blade can be elevated above the upper surface of the probe by means of movement of an actuator shaft. . . .
>
> As illustrated in FIG. **15**, when the actuator shaft **54** is moved toward the distal end of the probe **60** the blade **50** is caused to be elevated above the upper surface of the probe. The path of the distal end of the cutting blade is shown in dotted line. *In this embodiment the distal end of the cutting blade moves through a slightly arced path which is acceptable because the cutting blade is always moving away from the distal end of the probe*.

'284 Patent, col. 8, ll. 8-11, 19-27 (emphasis added). Therefore, even though Figures 17 and 19 depict paths of blade elevation that appear to be completely vertical (and thus perpendicular to the longitudinal axis of the probe), and even though these figures are described as causing the blade to

be elevated along a "vertical line" which was "desirable," *id*., col. 8, 40-42, 59-60, the inclusion of Figure 15 and its claimed "slightly arced path" undermine Arthrex's prosecution disclaimer argument and its proposed construction of "essentially perpendicular."

Accordingly, the Court concludes that the claimed function of the disputed term, "actuating means . . ." is for "extending said cutting blade outwardly from said probe in a manner such that said distal end portion of said cutting blade follows a path *which is in essence at a right angle* to the longitudinal axis of said housing, *and does not move distally relative to the probe during elevation*."

iv. Corresponding Structures

The second step in this claim construction analysis of a means-plus-function limitation is for the Court to "ascertain the corresponding structures in the written description that perform those functions." *Omega Eng'g*, 334 F.3d at 1321 (citing *St. Jude Med.*, 296 F.3d at 1113). A means-plus-function limitation "encompasses all of the structures in the specification that perform the recited function." *In re Guess*, 347 F. App'x 558, 560 (Fed. Cir. 2009) (citing *Ishida Co. v. Taylor*, 221 F.3d 1310, 1316 (Fed. Cir. 2000)). A disclosed structure is defined as corresponding "only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim." *Omega Eng'g*, 334 F.3d at 1321 (quoting *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)).

The specification of the '284 Patent discloses several corresponding structures which the Court finds to be "clearly linked" with the claimed function of the "actuating means" of the Patent. Most clearly linked with the claimed function are three sets of figures, each of which depict blade elevating means and a cut-away view of the probe after blade elevation: (1) Figure 14, which depicts "a side elevational cut-away view of the distal end of a surgical probe showing another blade elevating means, '284 Patent, col. 2, ll. 65-67; (2) Figure 15, which depicts "a side elevational cut-

away view of the probe of FIG. **14** showing the blade after it has been elevated," *id.*, col. 3, ll. 1-3; (3) Figure 16, which depicts "a side elevational cut-away of the distal end of a surgical probe showing another blade elevating means, *id.*, col. 3, ll. 4-6; (4) Figure 17, which depicts "a side elevational cut-away view of the probe of FIG. **16** showing the blade after it has been elevated, *id.*, col. 3, ll. 7-9; (5) Figure 18, which depicts "a side elevational cut-away view of the distal end of a surgical probe showing another blade elevating means," *id.*, col. 3, ll. 10-12; and (6) Figure 19, which depicts "a side elevational cut-away view of the probe of FIG. **18** showing the blade after it has been elevated, *id.*, col. 3, ll. 13-15.

While less clearly associated with the claimed function than the aforementioned three sets of figures, the Court concurs with MicroAire that Figures 12 and 13 are corresponding structures to the "actuating means . . . ." *See* MicroAire's Reply, at 9. The brief descriptions of Figures 12 and 13, unlike the aforementioned three sets of figures, do not utilize the term "blade elevating means," *id.*, col. 2, ll. 62-64, and to the extent these figures depict the mechanism for blade elevation, they do so without depicting the trajectory of the blade elevation and in significantly less detail than Figures 14 through 19. However, Figure 14 states that it depicts "a side elevational cut-away view of the distal end of a surgical probe showing *another* blade elevating means," *id.*, col. 2, ll. 65-67 (emphasis added), which certainly indicates that a prior figure had depicted the first disclosed blade elevating means. Furthermore, in the specification section entitled "Detailed Description of the Invention," the patentee recites with reference to Figures 12 and 13 a detailed description of a structure "to elevate the distal end of the blade **48** out through aperture **45** in a nearly vertical manner." *Id.*, col. 7, ll. 59-68, col. 8, ll. 1-7.

Finally, the Court finds that Figures 3 and 4 are clearly linked with the claimed function. The former "is a side elevational cut-away view of the distal tip of the probe of FIG. **1** (with blade

removed," while the latter is "a side elevational cut-away view of the probe of FIG. **1** with the cutting blade extended." *Id*., col. 2, ll. 39-42. Again, in the "Detailed Description" section of the specification, the patentee refers to Figure 3 and provides a description of the structure by which "the distal end of the cutting blade is caused to move from its retracted position to its extended position along a nearly vertical line. The vertical or extended position of the blade is shown in FIG. **4**." *Id*., col. 4, ll. 58-61.

4. Infringement

Having construed the disputed claims, the Court proceeds to determine whether MicroAire will likely establish that Arthrex's Centerline instrument infringes Claim 37 of the '284 Patent. On this point, the Court must answer in the negative.

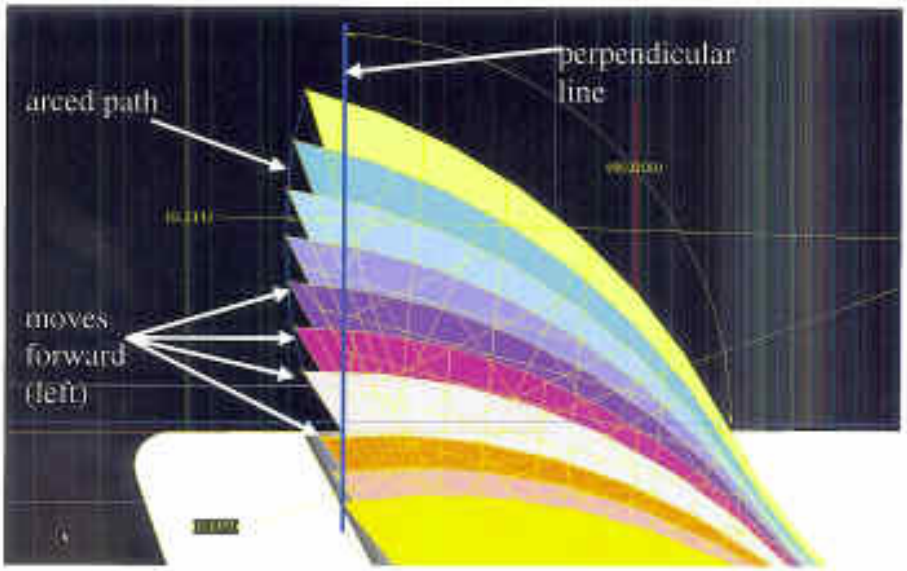
Literal infringement requires "that each and every limitation set forth in a claim appear in an accused product." *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004) (citing *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 796 (Fed. Cir. 1990)). "[L]iteral infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Omega Eng'g*, 334 F.3d at 1328 (citing *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1268-69 (Fed. Cir. 1999)). "Functional identity and either structural identity or equivalence are both necessary." *Id*.

Concerning functional identity, which is the first prong of this infringement analysis for a means-plus-function limitation, the Court must conclude that there is not functional identity between MicroAire's CTRS instrument and Arthrex's allegedly infringing Centerline instrument. As stated above, the Court has construed the function of the disputed means-plus-function limitation to be for "extending said cutting blade outwardly from said probe in a manner such that said distal end

portion of said cutting blade follows a path *which is in essence at a right angle* to the longitudinal axis of said housing, *and does not move distally relative to the probe during elevation*."

Pertinent to this inquiry, Arthrex has submitted a CAD figure showing the movement of Arthrex's blade upon elevation, which is reproduced below. Arthrex's Opposition, at 13.

CAD figure showing movement of Arthrex blade



While the Court finds that the path of this blade during elevation could be characterized as one "which is in essence at a right angle to the longitudinal axis of said housing," this figure clearly depicts distal movement of the blade both from: (1) the point of full retraction to the point of full extension; and (2) the point at which the blade breaks the plane of the upper surface of the probe to the point of full extension. This characterization of the path of blade extension is consistent with that of Arthrex's Senior Project Engineer responsible for Arthrex's Centerline instrument. Declaration of Mihaela Morar of Dec. 29, 2009, at ¶ 10 (docket no. 18, ex. A) (hereinafter "First Morar Declaration") ("As clearly shown relative to this perpendicular line, the tip of Arthrex's blade sweeps forward to the left (distal) end of the housing along an arced path as the blade is raised.").

Further, a composite series of still frames from a video recording taken of Arthrex's blade during extension, as well as a figure depicting mapped points of the blade dip during extension, evidence distal movement of the blade relative to the probe. Declaration of Mihaela Morar of Jan. 20, 2010, attachments B & C (docket no. 28) (hereinafter "Second Morar Declaration"). The competing evidence submitted by MicroAire in this regard is, at best, inconclusive concerning whether the blade of the Centerline instrument moves distally relative to the probe during elevation. At worst, these figures depict a small but visually observable amount of distal movement of the blade during elevation. *See* Declaration of Kenneth M. Welborn of Jan. 13, 2010, attachments B & C (docket no. 23) (hereinafter "Second Welborn Declaration").

Neither does the Court find persuasive MicroAire's argument that Arthrex's Centerline instrument "uses the same blade elevating mechanism that is shown in Figures 18 and 19 of the '284 Patent," and that because this figure is "statutorily incorporated by reference into the means plus-function claim term, actuating means," it has proven literal infringement. While MicroAire is correct that this figure is statutorily incorporated into the claim term "actuating means . . .," Figure 19 clearly depicts a path in which there is no distal movement of the blade relative to the body of the probe during extension. This characterization is supported by the very description of the figures set forth in the '284 Patent specification, which states that "[o]ther embodiments of surgical instruments are also provided in which the blade is elevated from the probe *in a manner such that the tip of the blade does not move distally relative to the probe*." '284 Patent, col. 2, ll. 15-18. Figure 19 is consistent with the Court's construction of the function of the disputed claim terms, and therefore does not salvage MicroAire's claim of literal infringement at this stage of the litigation.

Nor has MicroAire satisfied its burden of proving that Arthrex has infringed its '284 Patent

under the doctrine of equivalents.[6] This doctrine serves to define the scope of protection afforded under patent claims. "Devices which are equivalents of the invention defined by a patent claim are encompassed within the claim," *Decca Ltd. v. United States*, 420 F.2d 1010, 1014, 190 Ct. Cl. 454 (1970), and equivalence exists where "the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation." *Catalina Marketing*, 289 F.3d at 813 (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S.Ct. 854 (1950)). However, as the doctrine of prosecution disclaimer served to narrow the scope of the claims during claim construction, so too does the related doctrine of prosecution history estoppel serve to narrow the range of equivalents that are encompassed within the disputed claim.[7] "[P]rosecution history estoppel limits the range of equivalents available to the patentee by preventing recapture of subject matter surrendered during prosecution of the patent," but the prosecution history must "evince a clear and unmistakable surrender of subject matter" to so limit the equivalents encompassed within a claim. *PODS*, 484 F.3d at 1367 (citing cases).

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[6] It does not appear that MicroAire has alleged patent infringement under the doctrine of equivalents, as indeed Arthrex has argued. *See* Arthrex's Opposition, at 14 ("[MicroAire] does not assert that Arthrex's device infringes claim 37 under the doctrine of equivalents."). For example, MicroAire has argued that it has been "unable to identify any reported case applying the doctrine of prosecution disclaimer *to a case of literal infringement of a means-plus-function claim*, where, as here, the accused device employs a structure expressly disclosed in the specification of the patent in question." MicroAire's Reply, at 7 (emphasis added). Furthermore, MicroAire argues that it "does not assert that . . . prosecution disclaimer would apply if the Centerline product had employed an *equivalent* structure for actuating means, rather than one of the structures set forth in the specification. [This] question does not present itself, because the Centerline product uses the structure for an actuating means which is shown in Figures 18 and 19 of the '284 Patent and described in the narrative of the specification[.]" *Id*. at 7-8 (emphasis in original). Finally, MicroAire concludes its argument in the section of its Reply entitled "Defendant Uses the "Actuating Means . . ." Structure Shown in Figures 18-19 of the '284 Patent" with the contention that "[*t*]*here is literal infringement*." *Id*. at 11 (emphasis in original). Therefore, it appears that MicroAire has only argued literal infringement.

Because MicroAire has not explicitly argued that Arthrex infringed the '284 Patent under the doctrine of equivalents, the Court may be warranted in limiting its infringement analysis to literal infringement of this Patent. *See Omega Eng'g*, 334 F.3d at 1328 n.2 ("Because Omega did not pursue any argument that Raytek infringed the '880 patent under the doctrine of equivalents, we limit our discussion to literal infringement."). However, out of an abundance of caution, the Court will proceed to address whether, on the record at present, it is likely that Arthrex has infringed MicroAire's '284 Patent under the doctrine of equivalents.

[7] While the doctrine of prosecution history estoppel is inapplicable to the Court's claim construction inquiry for literal infringement, *see Southwall Techs.*, 54 F.3d at 1578, prosecution history "may be used not only in an estoppel

For the same reasons set forth in Section III(A)(3)(ii) and (iii) of this Memorandum Opinion, addressing prosecution disclaimer, *supra*, the Court finds that MicroAire is barred from asserting that Arthrex's device infringed the '284 Patent by equivalents. In particular, in order to overcome a rejection by the patent examiner, the patentee had explicitly distinguished the '284 Patent from the prior art on the basis that the actuating means in the new invention functioned to extend the cutting blade outwardly in a manner such that it did not move distally relative to the probe during extension. The specification of the '284 Patent is replete with indicia that the patentee surrendered this subject matter in order to obtain the Patent, notably: the Background of the Invention and Summary of the Present Invention sections of the Patent, 284 Patent, col. 1, ll. 10-14, 21-47, col. 2, ll. 15-18; the Detailed Description of the Invention section, *id*., col. 8, ll. 19-27, 37-42, 53-60; and the corresponding figures in the Patent previously identified. In response to the patent examiner's rejection of Original Claim 49 (now Claim 37), the Applicant's Amendment clearly stated: "[i]n contrast to that operation [in the prior art], the instrument of the present invention provides for elevation of the cutting blade along a path which is essentially perpendicular to the longitudinal axis of the probe. *In other words, in the present invention the tip of the cutting blade does not move distally relative to the probe during elevation. This is very significant* . . . ." Applicant's Amendment, at 22-23 (emphasis added). Accordingly, the Court finds that these were clear assertions made by the patentee during prosecution in order to secure the '284 Patent that would lead a competitor to "reasonably believe that the applicant had surrendered the relevant subject matter." *PODS*, 484 F.3d at 1368. MicroAire may not now "recapture" this subject matter by asserting infringement under the doctrine of equivalents.

Infringement is a question of fact, and the burden would be on MicroAire to prove

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context but also as a claim construction tool." *McGill Inc. v. John Zink Co.*, 736 F.2d 666, 673 (Fed. Cir. 1984).

infringement by showing, by a preponderance of the evidence, that Arthrex's Centerline product embodies all limitations (or their equivalents) in Claim 37 of the '284 Patent. *See Amgen Inc. v. F. Hoffman-LaRoche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). Because MicroAire seeks a preliminary injunction preventing Arthrex from making, using or selling an infringing carpal tunnel release instrument pending an ultimate resolution on the merits, MicroAire must establish that it is likely to succeed on the merits. *Winter*, 129 S.Ct. at 374. This means that, in light of the presumptions and burdens that will inhere at trial on the merits, that MicroAire, as the patentee, will likely prove that its competitor, Arthrex, infringes upon the '284 Patent. *Amazon.com*, 239 F.3d at 1350.

Based upon the Court's construction of the disputed means-plus-function limitation, and upon the evidence submitted, the Court cannot find that MicroAire is likely to prove that Arthrex's Centerline instrument infringes Claim 37 of the '284 Patent, and therefore, cannot find that MicroAire is likely to succeed on the merits.

B. IRREPARABLE HARM

A plaintiff seeking a preliminary injunction must then establish "that he is *likely* to suffer irreparable harm in the absence of preliminary relief." *Winter*, 129 S.Ct. at 374 (emphasis added). "Issuing a preliminary injunction based only on a *possibility* of irreparable harm is inconsistent with [the Supreme Court's] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id*. at 375-76 (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972, 117 S.Ct. 1865 (1997) (per curiam)) (emphasis added). As with the other factors, the plaintiff bears the burden of proving the likelihood of irreparable harm absent the Court's issuance of a preliminary injunction. *In re Microsoft Corp. Antitrust Litig.*, 333 F.3d 517, 526 (4th Cir. 2003) (citing *Direx Israel, Ltd. v. Breakthrough Medical Corp.*, 952 F.2d

802, 812 (4th Cir. 1991)).

At the preliminary injunction stage, "irreparable harm consists of harm that could not be sufficiently compensated by money damages or avoided by a later decision on the merits." *Canon, Inc. v. GCC Int'l, Ltd.*, 263 F. App'x 57, 62 (Fed. Cir. 2008) (citing Dan B. Dobbs, *Law of Remedies* 193-94 (2d ed. 1993)). Irreparable harm is generally suffered "when monetary damages are difficult to ascertain or are inadequate," *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994), and in the patent context, money damages will not necessarily be adequate to make the patentee whole. *See High Tech Medical Instrumentation, Inc. v. New Image Industries, Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) ("To be sure, 'the nature of the patent grant weighs against holding that money damages will always suffice to make the patentee whole.'" (citing *Hybritech, Inc. v. Abbott Lab.*, 849 F.2d 1446, 1456-57 (Fed. Cir. 1988))). Yet while courts have "repeatedly upheld the right of a patentee to a preliminary injunction and sometimes spoken of the possible inadequacy of money damages, there is no *presumption* that money damages will be inadequate in connection with a motion for an injunction pendente lite. Some evidence and reasoned analysis for that inadequacy should be proffered." *Nutrition 21 v. United States*, 930 F.2d 867, 871-72 (Fed. Cir. 1991) (emphasis in original). Because the burden of proving irreparable harm is on MicroAire as the patentee seeking the preliminary injunction, so too does it fall on MicroAire "to demonstrate that its potential losses cannot be compensated by monetary damages." *Automated Merchandising Sys., Inc. v. Crane Co.*, Nos. 2009-1157, 1164, 2009 WL 4878643, at *3 (Fed. Cir. Dec. 16, 2009).

Turning to the specific reasons advanced in support of a finding of irreparable harm, MicroAire argues that its "substantial investments in endoscopic carpal tunnel release training programs for surgeons," which it characterizes as "a form of goodwill," will suffer a reduction in

value as a result of the introduction of Arthrex's allegedly infringing Centerline product. Because Arthrex allegedly does not have similar training programs, and given the similarities in the products, MicroAire contends that "at least some surgeons will obtain training in endoscopic carpal tunnel release procedures at MicroAire-sponsored programs and then switch to [Arthrex's] infringing Centerline instrument." Due to its "substantial existing goodwill" as a result of the investment in surgeon training, MicroAire alleges that the adverse effect would be the same if Arthrex now started its own training programs because it would be "building goodwill on the base of MicroAire's existing investment." MicroAire also argues that it would face "market loss due to irreversible price erosion . . . as a result of direct price competition with the new, infringing Arthrex Centerline product." Finally, MicroAire broadly contends that there will be a "decline in the reputation of endoscopic carpal tunnel release surgery," as a whole, on the basis of Arthrex's introduction of this surgical instrument and its alleged "lower reputation for quality." The Court will address each of these arguments on irreparable harm in turn.

1. Goodwill

Neither the "difficulty of calculating losses in market share, nor speculation that such losses might occur," without more, warrants a finding of irreparable harm and the issuance of a preliminary injunction. *Nutrition 21*, 930 F.2d at 871; *see also Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990) (rejecting argument that potential for lost sales demonstrates manifest irreparable harm, because that position "would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances"). The loss of goodwill is a well-recognized basis for finding irreparable harm, and if MicroAire meets its burden of proving a loss of goodwill, it is immaterial whether, as Arthrex suggests, MicroAire's underlying concern is that "competition from Arthrex may ultimately result in a lost sale." *See e.g.*, *Medicine Shoppe Intern., Inc. v. S.B.S.*

Pill Dr., Inc., 336 F.3d 801, 805 (8th Cir. 2003) ("Loss of intangible assets such as reputation and goodwill can constitute irreparable injury."); *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996) (finding loss of revenue, goodwill, and research and development constitute irreparable harm); *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 552 (4th Cir. 1994) ("However, when the failure to grant preliminary relief creates the possibility of permanent loss of customers to a competitor or the loss of goodwill, the irreparable injury prong is satisfied."); *Blackwelder Furniture Co. v. Seilig Mfg. Co.*, 550 F.2d 189, 197 (4th Cir. 1977) (finding irreparable harm because reputational harm posed to general goodwill, due to the inability to fulfill catalog orders in excess of a certain value, was incalculable), *overruled on other grounds by Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342, 346-47 (4th Cir. 2009).

Goodwill is commonly defined as "[a] business's reputation, patronage, and other intangible assets that are considered when appraising the business, esp. for purchase," *Black's Law Dictionary* 763 (9th ed. 2009), and certain authorities have recognized that investments in educational and training programs, in connection with an organization's products or services, fall within the definition of goodwill. *See Breckenridge Pharm., Inc. v. Metabolite Labs., Inc.*, 444 F.3d 1356, 1365 (Fed. Cir. 2006) (noting, in dicta, that personal jurisdiction over a defendant corporation was supported when it "developed a valuable customer base and generated goodwill through advertising and educational initiatives that potentially enhanced the future sales of its exclusive distributor"); *Am. Registry of Radiologic Technologists v. McClellan*, No: 3:00-cv-2577, 2004 WL 377054, at *1 (N.D. Tex. Jan. 13, 2004) (finding that the educational programs of the national, voluntary certification organization for radiologic technologists were an investment of substantial time, money and effort in developing the goodwill associated with the organization's mark); *Genentech, Inc. v.*

Novo Nordisk A/S, 935 F.Supp. 260, 281 (S.D.N.Y. 1996) (finding that substantial sums spent on "programs involving education for patients and parents involved in [human growth hormone] therapy" were "[p]rograms to create goodwill"), *rev'd on other grounds by Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361 (Fed. Cir. 1997).

The Court concludes that MicroAire has not met its burden of proving that it would suffer irreparable harm absent injunctive relief, and that money damages would be an inadequate remedy in this case, on the basis of a loss of goodwill. Even less persuasive are the arguments advanced by MicroAire that "irreversible price erosion" and an "overall decline in the reputation of endoscopic carpal tunnel release surgery," occasioned by the introduction of Arthrex's product to market, satisfy the irreparable harm prong of this analysis.

MicroAire states that to ensure "the successful use of endoscopic carpal tunnel release instruments," and to prevent potential harm to patients by untrained surgeons, the company "limits sales of carpal tunnel release equipment to surgeons who have attended approved training programs." Declaration of Shannon Vaughn of Nov. 30, 2009, ¶ 7 (docket no. 7, ex. C) (hereinafter "Vaughn Declaration"). To this end, MicroAire states that it has made "long-term" and "substantial" investments in surgeon training. *Id*. at ¶¶ 6, 7. However, while MicroAire requires training in order to purchase its CTRS product and has invested in such training, Arthrex allegedly does not provide any similar training but instead advises that "the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's Directions For Use." Vaughn Declaration, Attachment. When Arthrex brings its product to market, MicroAire "expects that at least some surgeons will obtain training in endoscopic carpal tunnel release procedures at MicroAire-sponsored programs and then switch to the infringing Arthrex Centerline instrument rather than use the MicroAire CTRS instrument." *Id*. at ¶ 8. While

MicroAire characterizes this investment in training programs as "a form of goodwill" whose value is diminished upon the introduction of Arthrex's Centerline instrument to market, *id.* at ¶ 8, the Court must look past this bare characterization to determine the manner in which its value would be reduced. Although the authorities upon which MicroAire relies, namely the Fourth Circuit decision in *Multi-Channel*, "contain broad language regarding the availability of injunctive relief when the loss of future customers or harm to goodwill renders the calculation of damages difficult," they do not "hold[ ] that injunctive relief is automatic and required in such circumstances," and they "proceed[ ] to analyze the specific facts of the case before determining that the loss of future customers or the harm to goodwill makes damages difficult to ascertain." *Safeway, Inc. v. CESC Plaza Ltd. P'ship*, 261 F.Supp.2d 439, 469-70 (E.D. Va. 2003). An analysis of the specific facts in this case fails to elucidate how MicroAire will suffer harm to goodwill that makes damages difficult to ascertain.

The value of MicroAire's investment in surgeon training is partially intangible, as a means of bolstering the company's reputation in the medical community as a respected manufacturer of surgical instruments, and of building a relationship with its surgeon customers, and partially tangible, as such training necessarily serves as a vehicle for sales of its CTRS instrument. Crucially, as to the intangible elements of goodwill, it is both logically and factually unclear how MicroAire is adversely affected by the introduction of Arthrex's instrument. The reputational benefits MicroAire has accrued, and would continue to accrue, as a result of its investment in endoscopic carpal tunnel release procedure training would appear in no way to be diminished by the introduction of Arthrex's competitor product. If anything, MicroAire's "substantial" and "long-term" investment in these training programs would serve as a positive way to distinguish the company's reputation and product from Arthrex, should it choose not to place comparable emphasis on surgeon training programs. As

a factual matter, Arthrex has alleged to the contrary that it "conducts its own surgeon training on the use of the Centerline device," and that "[s]urgeon training is common in the industry and is used by manufacturers, such as Arthrex, to promote the sale of their instruments and products." First Morar Declaration, at ¶ 12. MicroAire has proffered no evidence to rebut the fact that Arthrex conducts its own surgeon training programs specific to the Centerline device. Therefore, MicroAire appears to argue a loss of goodwill based upon the attenuated theory that its investment in surgeon training programs is diminished because the training acquired in these programs is transferable to use of a competitor's product, even though that competitor provides training specific to its product.

Beyond the general statements that a loss of goodwill can establish irreparable harm, a careful reading of the authorities upon which MicroAire relies serves only to underscore that MicroAire has failed to establish a loss of goodwill, in terms of harm to its reputation, by the introduction of Arthrex's instrument. The *Multi-Channel* case cites *Blackwelder* for the proposition that "the potential loss of goodwill also support[s] a finding of irreparable harm." 22 F.3d at 552 (citing *Blackwelder***,** 550 F.2d at 197). However, in *Blackwelder*, the court found a harm to goodwill because "[w]ord of mouth grumbling of customers" and the inability to honor outstanding orders for Seilig furniture could result in Blackwelder acquiring a "reputation for general unreliability as a merchant." 550 F.2d at 197. Further, the loss of the Seilig line of furniture hampered Blackwelder's efforts to be a "full line" furniture discounter, which the court found to cause an "incalculable" harm to its reputation and goodwill. *Id*.; *see also Safeway, Inc.*, 261 F.Supp.2d at 470 (same). While MicroAire's investments in training programs can be characterized as goodwill, there is no comparable allegation that such programs will suffer any reputational harm by the introduction of the Arthrex instrument to market. There is no indication that MicroAire's customers will have a

lesser view of its training programs, its product, or the company as a whole,[8] to constitute the loss of goodwill contemplated in *Blackwelder* and *Multi-Channel*. MicroAire also relies upon *Sanofi-Synthelabo* for the same general proposition that harm to goodwill supports a finding of irreparable harm. *See* 470 F.3d at 1382-83. However, the underlying nature of the goodwill that was allegedly harmed in *Sanofi-Synthelabo* is similarly distinguishable from the instant case, as it concerns a "loss of consumer good will by customers who will have grown accustomed to lower prices for clopidogrel bisulfate [the active ingredient in Plavix® and the subject of the patent] with a generic product on the market." *Sanofi-Sythelabo v. Apotex, Inc.*, 488 F.Supp.2d 317, 343 (S.D.N.Y. 2006), *aff'd* 470 F.3d 1368 (Fed. Cir. 2006). Again, the harm to goodwill contemplated in *Sanofi-Synthelabo* was a lesser view of the attractiveness of the patentee's product in the eyes of the customer, resulting from the introduction of the allegedly-infringing product. Neither does MicroAire allege, as in *Sanofi-Sythelabo*, that the pricing scheme for its CTRS product will adversely affect the customers' perception of the product, and thereby result in harm to goodwill. Therefore, to the extent MicroAire seeks to establish irreparable harm on the basis of injury to reputation, whether or not it is characterized as an injury to goodwill, the Court finds that MicroAire has failed to so allege, much less satisfy its burden of proof, on this rationale.

As a basis for finding an injury to goodwill, MicroAire alleges that it is likely that a number of surgeons will receive training at MicroAire-sponsored programs, find the instruction transferable to the allegedly-infringing Arthrex Centerline instrument, and switch to the Centerline instrument. *See* Vaughn Declaration, at ¶ 8. It is true that "the threat of a permanent loss of customers and the potential loss of goodwill support a finding of irreparable harm." *Multi-Channel TV Cable Co.*, 22 F.3d at 552 (citing *Blackwelder*, 550 F.2d at 197); *see also Merrill Lynch, Pierce, Fenner & Smith,*

[8] The Court addresses MicroAire's contention that the introduction of Arthrex's product will lead to an "overall

Inc. v. Bradley, 756 F.2d 1048, 1055 (4th Cir. 1985) (finding, in support of a preliminary injunction, the fact that Merrill Lynch "faced irreparable, noncompensable harm in the loss of its customers"). However, besides the allegation that MicroAire has made "substantial" and "long-term" investments in its surgeon training programs, it has not alleged any basis upon which the Court could find that surgeons would find it more desirable to attend MicroAire's training programs and then switch to using Arthrex's surgical instrument, rather than utilize Arthrex's own training programs. Furthermore, a careful reading of these cases concerning a permanent loss of customers finds them easily distinguishable. In *Bradley*, the court stated that a preliminary injunction was warranted because the plaintiff faced "irreparable, noncompensable harm in the loss of its customers." 756 F.2d at 1055. However, the conduct at issue in *Bradley* was the active poaching of the plaintiff's customers from the defendant, a former employee, and the customers at issue were those with accounts at Merrill Lynch. *Id*. at 1051. This case is not comparable to a potential for loss of customers due to the introduction of a competitor-product in the market, and the Court finds more instructive the Federal Circuit's reasoning in *Illinois Tool Works* on when a loss of customers establishes irreparable harm in the patent context. *See Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679 (Fed. Cir. 1990). In that case, when the plaintiff had argued, *inter alia*, that "its 'potential lost sales' alone demonstrate 'manifest irreparable harm,'" the court responded that "acceptance of that position would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances." *Id*. at 683; *see also Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (noting that the court "do[es] not doubt that generic competition will impact Abbott's sales . . . but that alone does not establish that Abbott's harm will be irreparable"). Therefore, there clearly must be more than the potential for lost sales as a

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decline in the reputation of carpal tunnel release surgery," Vaughn Declaration, at ¶ 6, in Section III(B)(3).

result of a competitor product entering the market to establish irreparable harm.

Finally, MicroAire argues that the diminution of value of MicroAire's investment in training programs, which it characterizes as a form of goodwill, will be difficult to quantify or ascertain, and that supports a finding of irreparable harm. *See e.g.*, MicroAire's Memorandum in Support, at 16; MicroAire's Reply, at 14. Neither the "difficulty of calculating losses in market share, nor speculation that such losses might occur" warrant a finding of irreparable harm. *Nutrition 21*, 930 F.2d at 871. In other words, "the threat of loss of prospective customers, goodwill, or reputation may support a finding of irreparable harm, *so long as it is not too speculative*." *Gowan Co., LLC v. ACETO Agric. Chems.*, No. 09-cv-1124, 2009 WL 2028387, at *5 (D. Ariz. July 10, 2009) (citing *Rent-A-Center, Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir. 1991)) (emphasis added). MicroAire must show that it will experience a loss, at which point, a showing that monetary damages are difficult to ascertain or inadequate generally supports a finding of irreparable injury. *Multi-Channel*, 22 F.3d at 551. Upon MicroAire's argument that its training programs will suffer a diminution in value as a result of the introduction of Arthrex's product to market, the Court concludes that there is no reasonable basis for concluding that any such loss of value will occur. Without any allegations as to why surgeons may find MicroAire's training more attractive and then switch to using Arthrex's instrument in lieu of utilizing Arthrex's own training programs, and based upon the record at present, the Court finds that any allegation of loss in this respect is simply too attenuated to constitute a likelihood of irreparable harm.[9]

[9] Of course, at a later stage of this litigation, MicroAire may be able to prove by competent evidence the amount of loss it suffered from lost sales of its CTRS instrument as a result of the introduction of Arthrex's allegedly infringing Centerline instrument to market.

2. Irreversible Price Erosion

The Court finds even less persuasive MicroAire's argument that it will suffer "market loss due to irreversible price erosion and decline in MicroAire's customer base," in support of a finding of irreparable harm. Vaughn Declaration, at ¶ 6. While the prospect of irreversible price erosion has been held to establish irreparable harm under certain circumstances, those presently at issue before the Court are substantially different from those presented in the *Sanofi-Synthelabo* case, upon which MicroAire relies. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006).

In *Sanofi-Synthelabo*, the court, relying upon evidence presented by an economics expert as well as a Sanofi executive, found that the company

> would suffer irreversible price erosion in light of a complex pricing scheme that is directly affected by the presence of a generic product in the market. In particular, the court found that since Apotex's generic product entered the market, Sanofi has been forced to offer discounted rates and price concessions to third-party payors, such as health maintenance organizations, in order to keep Plavix® on a favorable pricing tier, which governs what consumers pay for that drug. … According to Sanofi, it is nearly impossible to restore Plavix® to its pre-launch price since the generic product entered the market.

470 F.3d at 1382. Thus, the peculiar effect of the introduction of a generic competitor to the name-brand drug in the pharmaceutical market was thus well-documented in *Sanofi-Synthelabo*, in part supported by evidence of the discounting required to keep Plavix® in competition with the generic competitor. Although this case similarly involves the sales in the healthcare field, MicroAire has presented no evidence that the market for surgical instruments involves third-party payors, discounting of the instrument sale price to certain classes of purchasers, or is any way comparably complex to the pharmaceutical market. *See Bettcher Indus., Inc. v. Bunzl USA, Inc.*, --- F.Supp.2d ----, 2010 WL 779689, at *12 (N.D. Ohio Feb. 26, 2010) (finding no irreparable harm, and distinguishing *Sanofi-Synthelabo*, because "[t]here is no complex pricing scheme here; rather, prices

appear to be dictated by competition between the two parties"). While MicroAire has argued as a general matter that it "anticipates market loss due to irreversible price erosion" upon the introduction of Arthrex's product to market, it has offered no evidence or rationale supporting this contention beyond the baseline economic principle that the introduction of a competitor product in the market will place downward pressure on prices. The mere assertion that allowing a competitor to keep producing and selling an allegedly infringing product will lead to irreversible price erosion, without more, is insufficient to constitute a finding of irreparable harm. *See Automated Merchandising Sys., Inc.*, 2009 WL 4878643, at *4. Therefore, as the Court has concluded that MicroAire has not carried its burden that it is likely to suffer irreparable harm on the basis of a loss of goodwill, neither has it done so on the basis of irreparable price erosion or loss of its customer base.

3. Decline in Reputation of Surgical Procedure

Finally, MicroAire summarily argues that it will suffer irreparable harm absent injunctive relief because Arthrex's "lower reputation for quality" will consequently result in an "overall decline in the reputation of endoscopic carpal tunnel release surgery." Vaughn Declaration, at ¶ 6. It is difficult to imagine under what extraordinary set of circumstances the introduction of a product with a "lower reputation for quality" would, instead of highlighting the higher quality of its competitors, reflect adversely upon the field as a whole. However, based solely upon conclusory statements as to Arthrex's reputation for quality, MicroAire has, upon this rationale, simply failed to meet its burden of proving the likelihood of irreparable harm absent the issuance of an injunction. *See Winter*, 129 S.Ct. at 374; *Direx Israel*, 952 F.2d at 812.

C. BALANCE OF THE EQUITIES & PUBLIC INTEREST

The Court has concluded, *supra*, that MicroAire is neither likely to succeed on the merits, nor is likely to prove irreparable harm. Where either of these prongs of the test for a preliminary

injunction set forth in *Winter* is not satisfied, the Court may not issue the injunction. However, the Court is charged with weighing all of the factors, *Sofamor Danek Group*, 74 F.3d at 1219, and after consideration of the remaining two factors, being the balance of equities and whether the injunction is in the public interest, the Court finds that they do not compel a contrary result.

In support of its contention that the balance of equities favors the issuance of a preliminary injunction, MicroAire cites the risk that the '284 Patent will be nearly expired by the time a final adjudication on the merits is reached in this litigation. MicroAire's Memorandum in Support, at 6. In effect, MicroAire argues that a party should not be able to infringe upon a patent in the last years of its term, banking upon the assumption that the patent holder will find it less economical to litigate a complex and time consuming patent case in the patent's waning years than settle or acquiesce in the infringement. In response, Arthrex argues that the Court should afford the '284 Patent no special treatment simply because its expiration is approaching. The Court finds merit with both parties' arguments. Indeed, "[p]atent rights do not peter out as the end of the patent term . . . is approached," however, the Court does not accept any argument "that the need for injunctive relief necessarily is more imperative as the end of the patent term approaches." *Woodard v. Sage Prods., Inc.* 818 F.2d 841, 854 (Fed. Cir. 1987). In any event, this factor, as argued by MicroAire, rests upon a determination that MicroAire is likely to succeed on the merits and has shown it is likely to suffer irreparable harm absent the preliminary injunction. *See* MicroAire's Memorandum in Support, at 16. It has not done so.

Similarly, as to whether the public interest supports the issuance of a preliminary injunction, MicroAire argues that "[b]y preventing patent infringement, the requested preliminary injunction would be consistent with the public policies embodied in the Patent Act." MicroAire's Memorandum in Support, at 17. Conversely, Arthrex argues that "the public interest is not served

here because [MicroAire] cannot establish a likelihood of success on the merits." Arthrex's Opposition, at 19. This argument, and other arguments arising therefrom, are inextricably intertwined with the Court's determination on MicroAire's likelihood of success on the merits. *See Andrx. Pharm.*, 452 F.3d at 1348 ("Although the public interest inquiry is not necessarily or always bound to the likelihood of success on the merits, in this case absent any other relevant concerns, we agree . . . that the public interest is best served by enforcing patents that are likely valid and infringed. As Abbott did not establish a likelihood of success on the merits, we conclude that the public interest is best served by denying the preliminary injunction.").

IV. CONCLUSION

To recapitulate, *supra*, MicroAire has not established that it is likely to succeed on the merits. In particular, the disputed term "actuating means" is properly construed as disclaiming any claim to "actuating means" by which the blade of the surgical instrument moves distally (forward) relative to the body of the instrument during its elevation. The disputed term "essentially perpendicular" is properly construed as only reciting that the blade follows a path which is in essence at a right angle to the longitudinal axis of the instrument, and not a path which necessarily forms a right angle with the longitudinal axis. As Arthrex's allegedly infringing surgical instrument employs "actuating means" by which the blade moves distally relative to its body during elevation (even though its blade follows a path which is in essence at a right angle to the instrument's longitudinal axis) MicroAire has not established a claim of literal infringement of its patent, or infringement under the doctrine of equivalents. Furthermore, MicroAire has not established a likelihood of irreparable harm, whether based upon the threatened loss of goodwill, irreversible price erosion, or general decline in reputation of the surgical procedure at issue. The failure to satisfy either likelihood of success or irreparable harm factor would justify the Court's denial of a

preliminary injunction. The Court's consideration of the two remaining factors, relating to the balance of equities and public interest, do not compel a contrary result. Accordingly, MicroAire's Motion for Preliminary Injunction will be DENIED, in an Order, to follow.

The Clerk of the Court is hereby directed to send a certified copy of this Memorandum Opinion, and the accompanying Order, to all counsel of record.

Entered this 3rd day of June, 2010.

NORMAN K. MOON
UNITED STATES DISTRICT JUDGE